DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

OCT 26 2004

WARNING LETTER

VIA FEDERAL EXPRESS

Anthony Masciangelo
The One and Only Fashion Beauty Group, Inc.
74 Simcoe Road
Kettleby, Ontario
Canada LOG 1JO

Dear Mr. Masciangelo:

Investigators for the United States Food and Drug Administration (FDA) have examined a number of shipments of plano (i.e., zero-powered or non-corrective) tinted contact lenses that your firm has shipped to consumers in the United States. We have also reviewed your web site, www.onlyonefix.com. Our examination and review have revealed a serious regulatory problem involving your lenses.

Because your firm's plano tinted contact lenses are intended to change the appearance of the normal eye in decorative fashion, they are cosmetics within the meaning of 21 U.S.C. § 321(i). Your distribution of plano tinted contact lenses without the involvement of a qualified eye care professional causes your lenses to be adulterated under 21 U.S.C § 361(a). That section provides that a cosmetic shall be deemed to be adulterated "if it bears or contains a poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual."

Your lenses also are misbranded under 21 U.S.C. § 362(a). A cosmetic is deemed to be misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. § 362(a). Labeling is false or misleading if it "fails to reveal facts . . . material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . thereof or under such conditions of use as are customary or usual."

21 U.S.C. § 321(n). The Consumer Guide distributed with your lenses states that the lenses are "Safe and Easy to Use," but fails to reveal material facts regarding the consequences that may result from use of the lenses under the labeled, customary, or usual conditions of use. For example, contact lens wear may result in serious injury to the eye, and eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. In addition, although your Consumer Guide recommends that first time lens users consult an eye care professional to see that their eyes are suitable for lens wear, your labeling does not reveal that some persons are not suitable for contact lens wear due to the presence of ocular or systemic health conditions, nor does it reveal the consequence that lens wear by a person who is not a suitable candidate for contact lens wear poses a greater risk of serious eye injury.

This letter is not intended to identify all violations of the Federal Food, Drug, and Cosmetic Act (Act) that apply to the marketing of your plano tinted contact lenses. It is your firm's responsibility to ensure that these products are in compliance with the Act and FDA regulations.

The plano tinted contact lenses that your firm imports or offers for import into the United States are subject to refusal of admission under 21 U.S.C. § 381(a), in that they appear to be adulterated and misbranded. FDA may take steps to detain these products without physical examination, until these violations are corrected.

In order to remove the products from detention, you should provide a written response to this warning letter describing the steps you have taken to correct the violations described in this letter. We will notify you whether your response is adequate.

Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the violations described in this letter. Please direct your response to: Keisha Thomas, 2098 Gaither Road (HFZ-331), Rockville, MD 20850.

If you have questions, please contact Betty W. Collins, Director, Division of Enforcement A. If you have any technical questions please direct them to Keisha Thomas at (240) 276-0115.

Sincerely yours,

Larry D. Spears for

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health